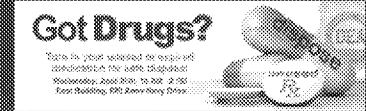


Ultimate User Disposal of Medicines

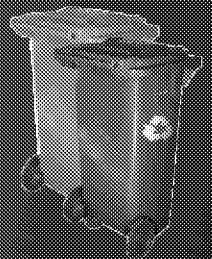
National Take-Back Events: Take-back events are a good way to remove expired, unwanted, or unused medicines from the home.



Law Enforcement Collection Bins: Collection bins installed by our Law Enforcement Partners are a good way to remove expired, unwanted, or unused medicines from the home.



Disposal in Household Trash: Mix medicines (do not crush tablets or capsules) with substances such as kitty litter or used coffee grounds and place the mixture in a container such as a sealed plastic bag and throw the container in your household trash.



Disposal by Flushing: Some medicines have specific disposal instructions that indicate they should be flushed down the sink or toilet when they are no longer needed.



Law Enforcement

- Law enforcement officers, acting to enforce laws regarding the abandonment of controlled substances, may receive controlled substances from ultimate users.
- Law enforcement must safeguard the controlled substances and ensure that they are destroyed properly.
- Law enforcement must be present during the destruction of the controlled substances.

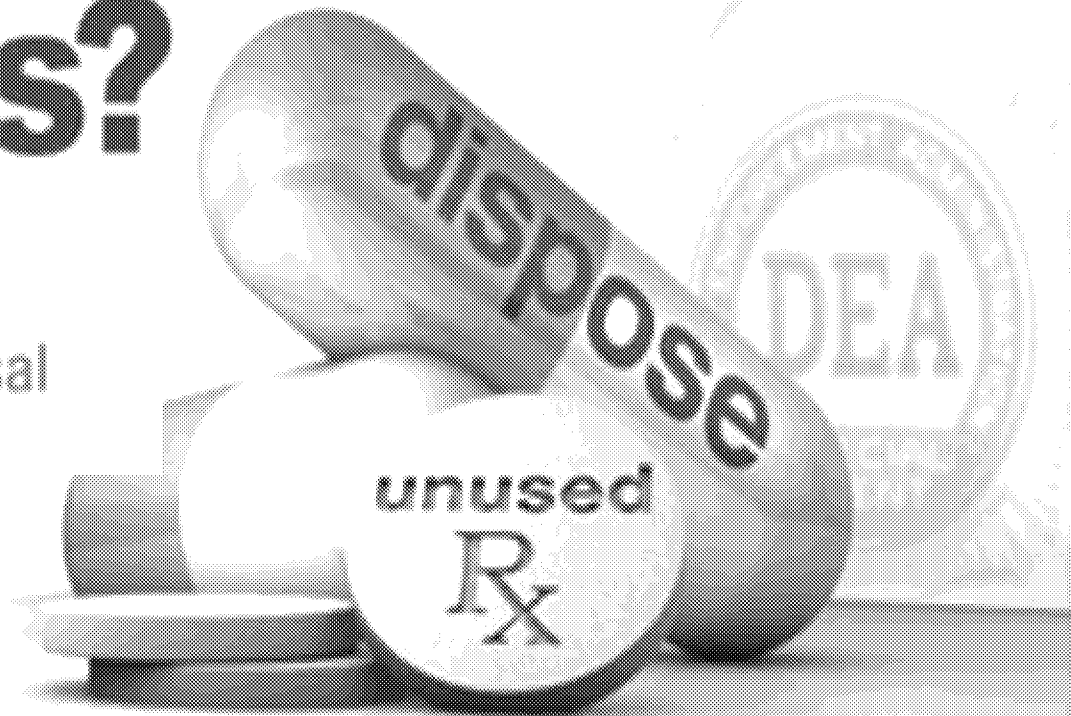
National Take Back Initiative

April 27, 2013

Got Drugs?

Turn in your
unused or expired
medication for safe disposal
Saturday, April 27, 2013

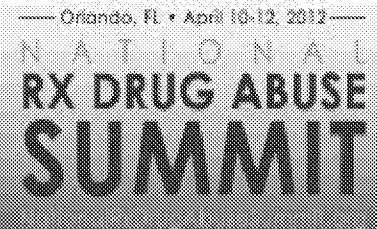
Click here
for a collection
site near you.



SUMMIT
National Drug Abuse Summit

Nationwide Take-back Initiative

- On September 30, 2010, 122 tons of prescription drugs collected
- On April 30, 2011, 188 tons of prescription drugs collected
- On October 29, 2011, 189 tons of prescription drugs collected
- On April 28, 2012, approximately 276 tons of prescription drugs collected
- On September 29, 2012, approximately 244 tons of prescription drugs collected



Next Nationwide Take-back Event

April 27, 2013

Secure and Responsible Drug Disposal Act of 2010

- Enacted in October 2010 (Pub. L. 111-273, codified at 21 U.S.C. 822(g) and 823(b)(3))
- Act allows an ultimate user to “deliver” a controlled substance “to another person for the purpose of disposal” in accordance with regulations issued by DEA
- If the ultimate user dies while in lawful possession of the controlled substance, then any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal.
- DEA may also, by regulation, authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF.
- DEA is working to promulgate regulations to implement this Act. DEA must consider:
 - Public health and safety
 - Ease and cost of program implementation
 - Participation by various communities
 - Diversion Control
- Participation is voluntary. DEA may not require any person to establish or operate a delivery or disposal program.

ONDCP Guidelines

- ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (2/20/07).
- Advise public to flush medications only if the prescription label or accompanying patient information specifically states to do so.
- ONDCP recommends a minimal deactivation procedure, and disposal in common household trash.

PROZAC (?) FISH



MEDICINES RECOMMENDED FOR DISPOSAL BY FLUSHING

This list from FDA tells you what expired, unwanted, or unused medicines you should flush down the sink or toilet to help prevent danger to people and pets in the home. Flushing these medicines will get rid of them right away and help keep your family and pets safe.

FDA continually evaluates medicines for safety risks and will update the list as needed.

Medicine	Active Ingredient
Abstral, tablets (sublingual)	Fentanyl
Actiq, oral transmucosal lozenge *	Fentanyl Citrate
Avinza, capsules (extended release)	Morphine Sulfate
Daytrana, transdermal patch system	Methylphenidate
Demerol, tablets *	Meperidine Hydrochloride
Demerol, oral solution *	Meperidine Hydrochloride
Diastat/Diastat AcuDial, rectal gel	Diazepam
Dilaudid, tablets *	Hydromorphone Hydrochloride
Dilaudid, oral liquid *	Hydromorphone Hydrochloride
Dolophine Hydrochloride, tablets *	Methadone Hydrochloride
Duragesic, patch (extended release) *	Fentanyl
Embeda, capsules (extended release)	Morphine Sulfate; Naltrexone Hydrochloride
Exalgo, tablets (extended release)	Hydromorphone Hydrochloride
Fentora, tablets (buccal)	Fentanyl Citrate
Kadian, capsules (extended release)	Morphine Sulfate
Methadone Hydrochloride, oral solution *	Methadone Hydrochloride
Methadose, tablets *	Methadone Hydrochloride
Morphine Sulfate, tablets (immediate release) *	Morphine Sulfate
Morphine Sulfate, oral solution *	Morphine Sulfate
MS Contin, tablets (extended release) *	Morphine Sulfate
Nucynta ER, tablets (extended release)	Tapentadol
Onsolis, soluble film (buccal)	Fentanyl Citrate
Opana, tablets (immediate release)	Oxycodone Hydrochloride
Opana ER, tablets (extended release)	Oxycodone Hydrochloride
Oramorph SR, tablets (sustained release)	Morphine Sulfate
Oxecta, tablets (immediate release)	Oxycodone Hydrochloride
Oxycodone Hydrochloride, capsules	Oxycodone Hydrochloride
Oxycodone Hydrochloride, oral solution	Oxycodone Hydrochloride
Oxycontin, tablets (extended release) *	Oxycodone Hydrochloride
Percocet, tablets *	Acetaminophen; Oxycodone Hydrochloride
Percodan, tablets *	Aspirin; Oxycodone Hydrochloride
Xyrem, oral solution	Sodium Oxybate

*These medicines have generic versions available or are only available in generic formulations.

List revised: January 2012

Pharmaceuticals

Legend Drugs v. Controlled Substances

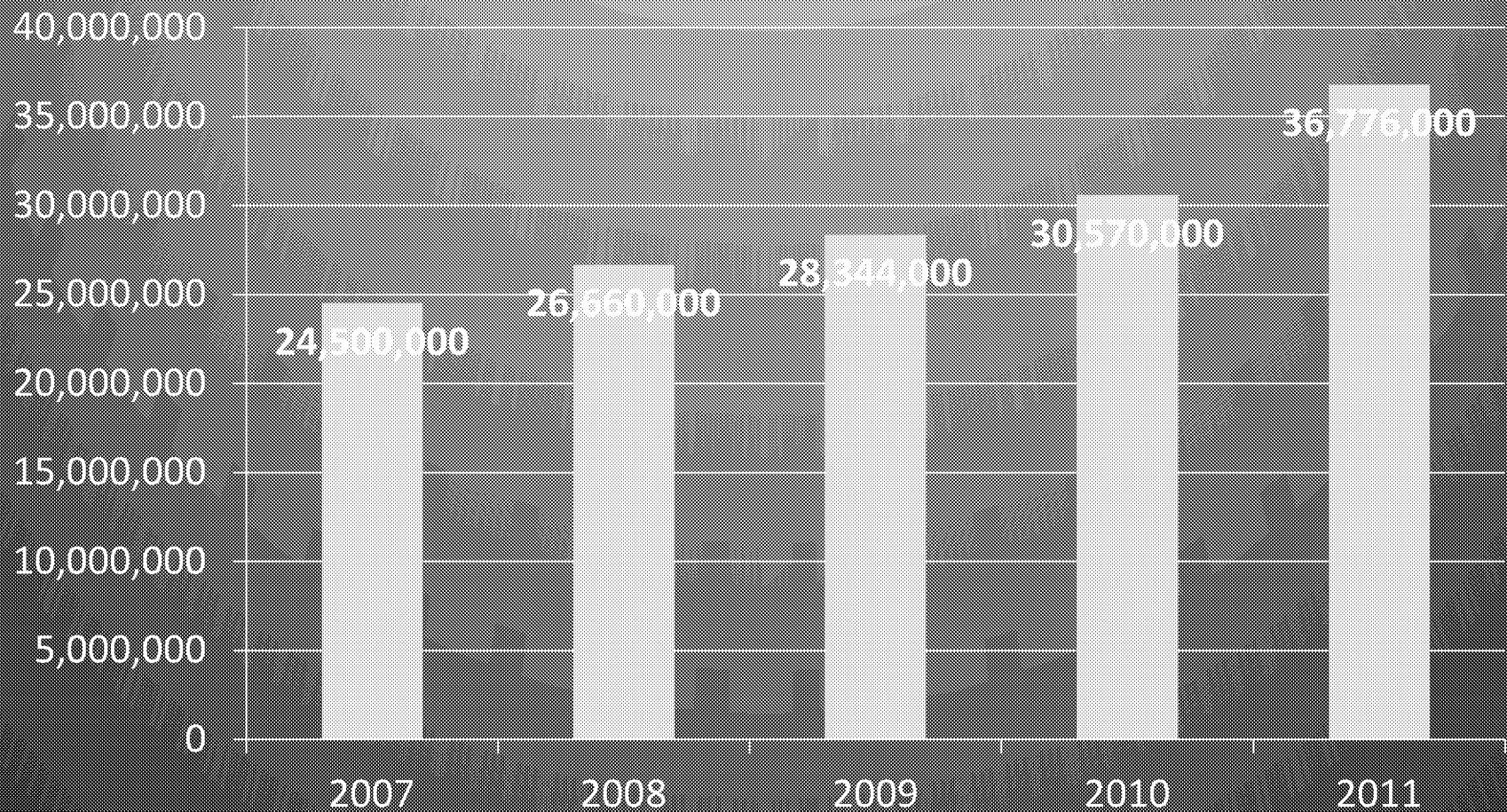
Legend Pharmaceuticals



Non-Controlled Substances

- Analgesic:
 - Tramadol (Ultram®, Ultracet®)
- Muscle Relaxant:
 - Cyclobenzaprine (Flexeril®)

Tramadol Prescriptions



Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012

NFLIS Estimated Tramadol Reports

and Percentage of Total Narcotic Analgesics

January – June

Year (Jan – June)	Estimated Reports	% of Total Narcotic Analgesics
2009	557	0.99%
2010	704	1.04%
2011	720	1.09%
2012	957	1.50%

Source: U.S. Drug Enforcement Administration, Office of Diversion Control. National Forensic Laboratory Information System (NFLIS): Midyear Reports (2009-2012).

Cyclobenzaprine

(Amrix®, Flexeril®, Fexmid®)

- A skeletal muscle relaxant prescribed for acute temporary muscle spasms caused by local trauma or strain.
- Marketed in the United States since 1977 (by Merck Com.).
- Currently non-controlled under the CSA.
- Chemical structure related to tricyclic antidepressant drugs (e.g., amitriptyline)
- Cyclobenzaprine, similar to other skeletal muscle relaxants, is being diverted and abused

Controlled Pharmaceuticals

Prescription Requirements

	Schedule II	Schedule III	Schedule IV	Schedule V
Written	Yes	Yes	Yes	Yes
Oral	Emergency Only*	Yes	Yes	Yes
Facsimile	Yes**	Yes	Yes	Yes
Refills	No	Yes#	Yes#	Yes#
Partial Fills	Yes***	Yes	Yes	Yes

* Must be reduced in writing, and followed by sign, hard copy of the prescription.

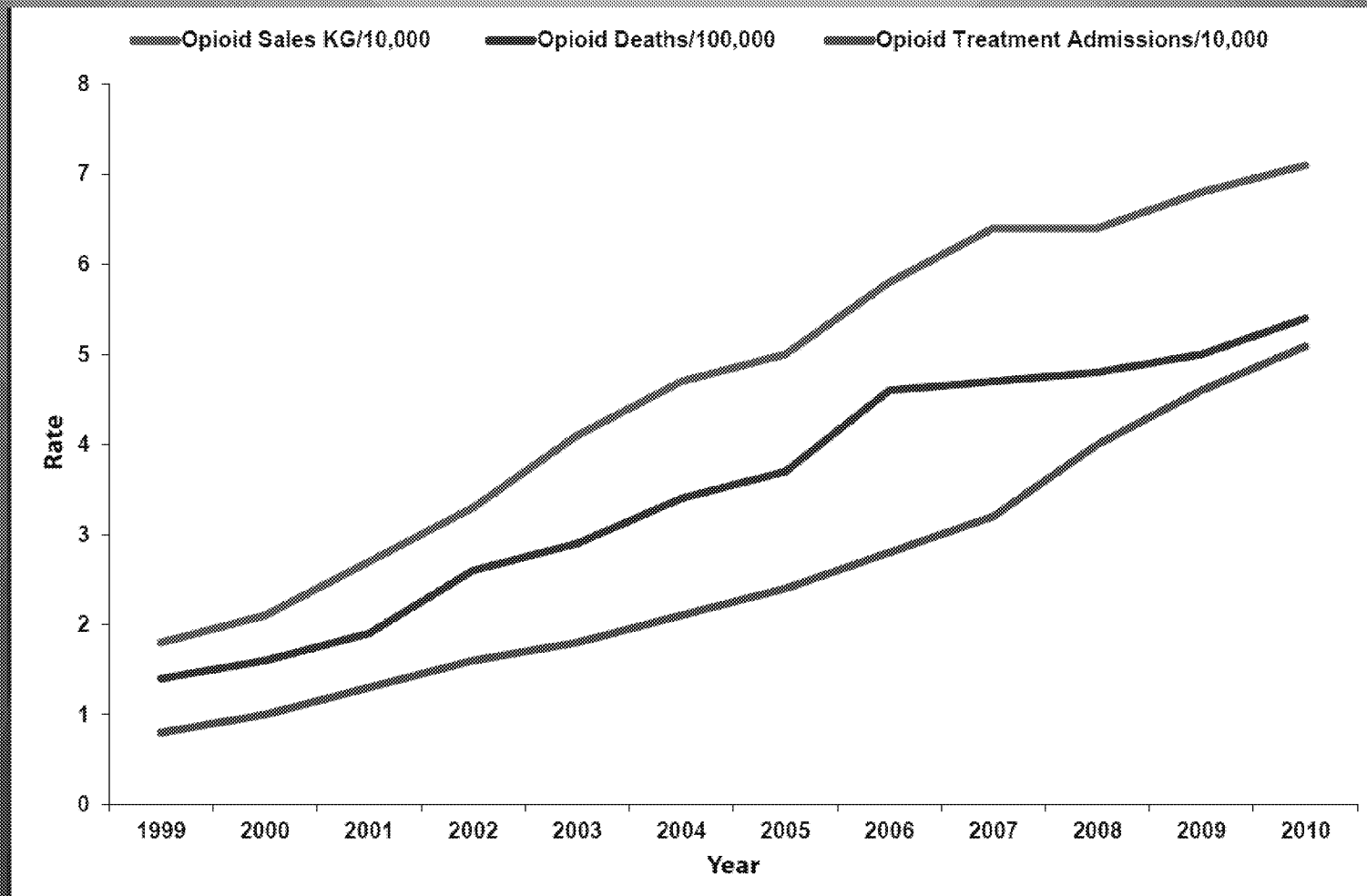
** A signed, hard copy of the prescription must be presented before the medication is dispensed.

*** 72 hour time limitation.

With medical authorization, up to 5 in 6 months.

Opiates

U.S. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, 1999-2010



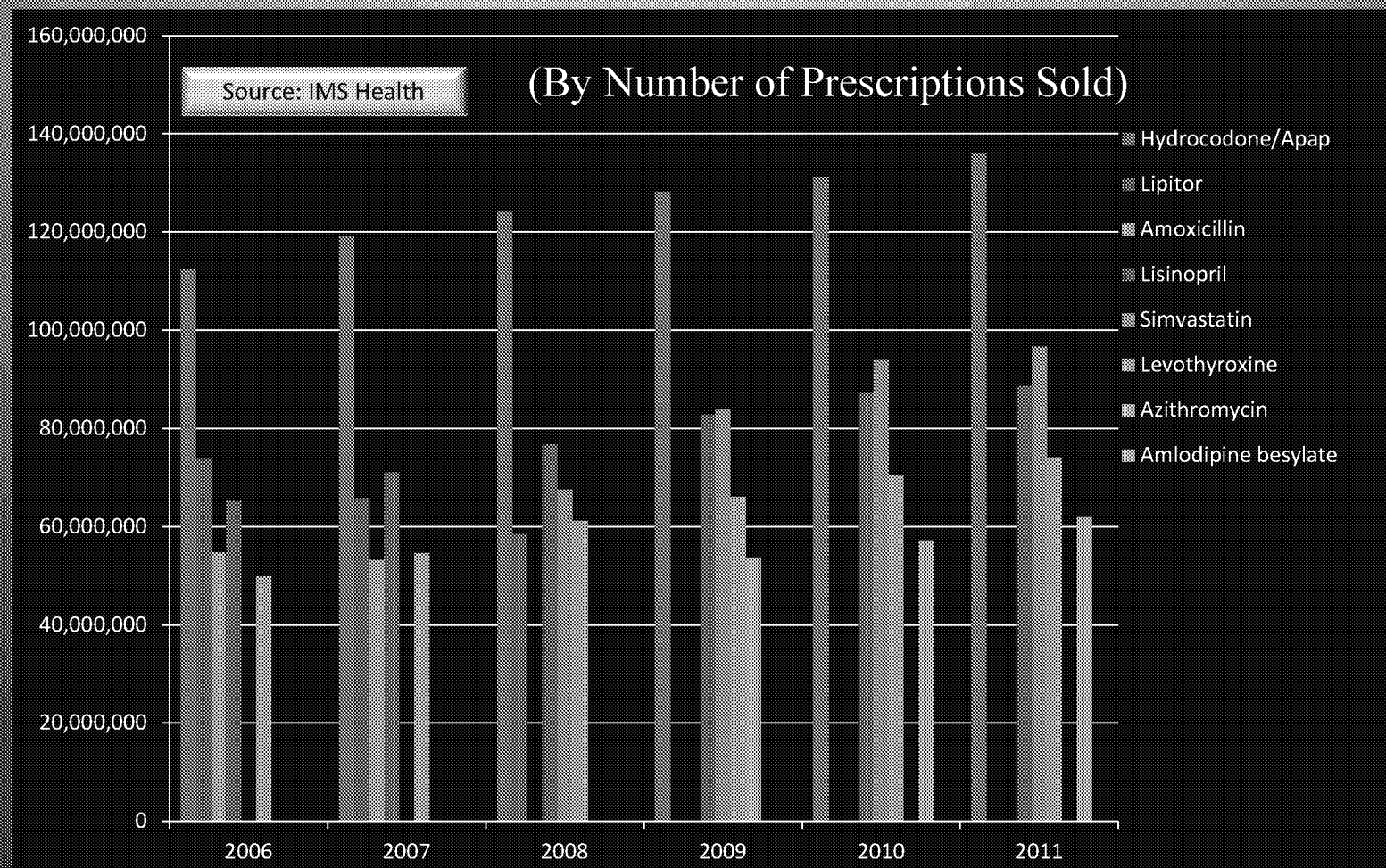
Source: National Vital Statistics System (NVSS),
DEA's Automation of Reports and
Consolidated Orders System, SAMHSA's
Treatment Episode Data Set

U.S. Drug Enforcement Administration /
Operations Division / Office of Diversion
Control

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

Top Five Prescription Drugs Sold in the U.S. (2006-2011)



Top 25 U.S. Pharmaceutical Products Dispensed by Prescription*

		Total DSC by 3rd DSC				
		2007	2008	2009	2010	2011
Total US Prescription Market		3,825	3,866	3,949	3,993	4,024
1	hydrocodone/acetaminophen	119.2	124.1	128.2	131.2	136.0
2	simvastatin	47.9	67.5	83.8	94.1	96.6
3	lisinopril	71.1	76.8	82.8	87.4	88.6
4	levothyroxine sodium	54.6	61.2	66.0	70.5	74.1
5	amlodipine besylate	27.9	44.6	51.3	57.2	62.1
6	omeprazole (RX)	26.6	35.1	45.4	53.4	59.3
7	azithromycin	46.3	51.0	53.8	52.6	55.3
8	amoxicillin	53.2	50.9	52.4	52.3	53.8
9	metformin HCL	40.2	42.3	44.3	46.9	48.4
10	hydrochlorothiazide	48.5	48.5	47.9	47.8	48.1
11	alprazolam	39.8	41.7	43.9	46.3	47.8
12	furosemide	44.2	44.1	43.5	43.4	42.1
13	Lipitor®	65.8	58.5	51.7	45.3	40.8
14	zolpidem tartrate	16.0	29.9	35.1	38.0	39.4
15	metoprolol tartrate	31.6	32.6	41.1	38.9	37.8
16	citalopram HBR	17.8	22.4	27.1	32.1	37.7
17	sertraline HCL	31.6	32.7	34.2	35.7	37.2
18	metoprolol succinate	21.0	41.5	26.9	33.0	34.5
19	prednisone	25.9	27.1	27.8	28.7	33.7
20	atenolol	44.7	41.8	39.3	36.3	33.3
21	gabapentin	20.0	22.2	25.4	29.3	33.2
22	tramadol HCL	19.1	21.8	24.1	26.8	32.9
23	oxycodone/acetaminophen	25.9	28.4	30.2	31.9	32.8
24	ibuprofen (RX)	27.7	28.5	30.3	31.1	32.6
25	warfarin sodium	28.8	30.2	31.6	32.0	30.9

*

Source:



National Prescription Audit™

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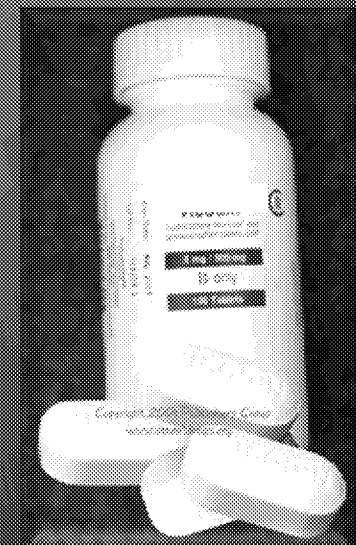
Updated February 23, 2013

Top 50 Generic Drugs by Total Prescriptions 2010

Rank	Drug	Total Rxs	Change from Previous Year	Rank	Drug	Total Rxs	Change from Previous Year
1	Hydrocodone/APAP	122,806,850	2.10%	26	Lorazepam	23,428,627	3.70%
2	Lisinopril	76,901,813	4.30%	27	Warfarin	23,388,338	1.50%
3	Simvastatin	76,771,821	4.90%	28	Clonazepam	23,085,065	4.00%
4	Levothyroxine	68,222,152	8.20%	29	Fluticasone nasal	22,447,832	19.70%
5	Amoxicillin	51,083,822	-0.60%	30	Cyclobenzaprine	22,240,071	7.30%
6	Amlodipine besylate	50,186,652	11.70%	31	Cephalexin	21,943,482	2.70%
7	Azithromycin	48,756,188	-2.10%	32	Trimethoprim/sulfa	21,345,723	4.50%
8	Alprazolam	46,201,182	3.90%	33	Fexofenadine	20,430,430	27.50%
9	Hydrochlorothiazide	45,838,017	-0.80%	34	Amoxicillin/pot clav	20,234,873	1.20%
10	Omeprazole	44,795,175	15.40%	35	Ciprofloxacin HCl	20,063,382	1.80%
11	Metformin	41,932,689	4.70%	36	Pravastatin	20,026,786	17.90%
12	Furosemide oral	36,583,895	-0.10%	37	Trazodone HCl	18,786,495	6.50%
13	Metoprolol tartrate	34,707,807	-0.50%	38	Lovastatin	17,509,951	13.50%
14	Atenolol	33,839,806	-11.00%	39	Triamterene/HCTZ	17,201,037	-7.00%
15	Sertraline	33,409,838	8.90%	40	Carvedilol	16,681,336	8.30%
16	Metoprolol succinate	32,224,000	12.00%	41	Alendronate	16,177,014	-6.90%
17	Zolpidem tartrate	29,719,569	-2.80%	42	Ranitidine HCl	14,699,414	6.60%
18	Oxycodone/APAP	28,705,243	6.80%	43	Meloxicam	14,645,167	2.90%
19	Citalopram HBR	27,993,635	9.40%	44	Diazepam	14,584,147	7.10%
20	Gabapentin	26,865,557	14.00%	45	Naproxen	14,297,759	10.30%
21	Ibuprofen	26,256,548	3.20%	46	Propoxyphene-N/APAP	14,274,354	-18.70%
22	Prednisone oral	25,529,463	-2.70%	47	Fluconazole	13,938,887	4.80%
23	Tramadol	25,527,796	10.30%	48	Methylprednisolone tabs	13,659,852	11.30%
24	Lisinopril/HCTZ	24,538,247	8.00%	49	Doxycycline	13,199,430	1.90%
25	Fluoxetine	24,473,994	6.80%	50	Paroxetine	12,979,368	-14.40%

Hydrocodone, APAP C-III

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- “Cocktail” or “Holy Trinity”
 - Hydrocodone
 - Soma [®] / carisoprodol
 - Alprazolam / Xanax[®]
- Street prices: \$2 to \$10+ per tablet depending on strength & region



State Ranking* - Hydrocodone

January 1 – December 31, 2011

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	405,692,065	12	IL	92,977,840	23	VA	55,100,651	34	CO	18,452,400	45	AK	6,041,200
2	TX	340,313,340	13	FL	90,012,630	24	WV	50,784,470	35	NM	17,284,770	46	WY	3,655,570
3	MI	172,654,340	14	NC	86,619,248	25	OR	49,989,655	36	NE	17,208,499	47	RI	3,571,380
4	AL	134,461,800	15	LA	82,584,490	26	WI	45,882,760	37	MA	15,920,820	48	VT	2,103,920
5	KY	129,026,114	16	MS	77,669,630	27	MN	32,918,294	38	MD	15,372,420	49	NH	1,740,840
6	TN	122,258,515	17	PA	76,070,466	28	UT	31,039,500	39	MT	11,065,910	50	PR	1274220
7	GA	111,364,050	18	IN	64,032,062	29	IA	29,605,860	40	SD	9,212,040	51	DE	823780
8	OK	102,103,000	19	AR	63,705,310	30	AZ	29,201,725	41	ND	9,067,980	52	DC	653,430
9	OH	94,175,600	20	WA	62,896,030	31	NJ	20,979,530	42	HI	8,500,500	53	VI	408,000
10	MO	93,914,780	21	KS	59,379,830	32	ID	20,976,760	43	CT	8,372,250	54	GU	196,300
11	NY	93,900,590	22	SC	55,883,580	33	NE	20,409,240	44	ME	7,924,050			

** Business Activity—Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

State Ranking* - Hydrocodone

January 1– December 31, 2011

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	26,596,905	12	MD	1,056,089	23	OH	531,337	34	MN	214,474	45	MT	61,460
2	GA	3,650,814	13	VA	1,034,924	24	NJ	522,515	35	ND	186,249	46	SD	58,412
3	IL	2,535,828	14	TX	1,002,407	25	CT	408,858	36	IA	164,389	47	ME	48,402
4	FL	2,448,494	15	KY	965,850	26	OR	382,882	37	DE	150,950	48	RI	29,827
5	NV	2,435,532	16	CO	940,617	27	WI	376,634	38	KS	139,620	49	DC	28,654
6	TN	2,429,834	17	NY	690,759	28	HI	376,252	39	KS	132,850	50	VT	26,800
7	PA	1,837,008	18	SC	655,614	29	LA	371,093	40	UT	111,602	51	NH	22,472
8	AL	1,454,378	19	MO	649,763	30	MI	366,637	41	WV	99,190	52	GU	6,200
9	IN	1,326,323	20	WA	596,102	31	ID	247,450	42	AR	97,303	53	RP	2,200
10	AZ	1,161,886	21	OK	594,602	32	AK	235,769	43	NE	78,756	54	VI	1,800
11	MI	1,062,674	22	NC	581,264	33	NM	226,786	44	WY	70,360			

** Business Activity- Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

State Ranking* - Hydrocodone

January 1– September 30, 2012

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	23,776,920	12	MD	741,978	23	OH	346,787	34	AK	159,271	45	NE	50,104
2	GA	2,409,068	13	TX	701,126	24	HI	345,827	35	MN	139,325	46	SD	42,280
3	IL	2,050,379	14	CO	620,493	25	MS	330,759	36	IA	112,594	47	ME	37,500
4	TN	1,647,726	15	NV	564,154	26	NJ	325,776	37	ND	106,930	48	RI	22,667
5	PA	1,646,148	16	NC	500,302	27	WA	310,658	38	KS	93,795	49	DC	21,110
6	AL	1,324,943	17	MO	493,318	28	WI	266,806	39	DE	85,458	50	VT	14,900
7	MI	883,366	18	NY	456,281	29	LA	244,062	40	UT	79,160	51	NH	11,818
8	IN	850,550	19	OK	408,606	30	OR	224,877	41	MA	69,290	52	GU	3,500
9	VA	812,750	20	KY	405,044	31	ID	176,600	42	WY	68,450	53	PR	2,500
10	AZ	806,259	21	SC	374,024	32	WV	167,788	43	AR	66,270	54	VI	700
11	FL	754,979	22	CT	360,517	33	NM	161,810	44	MT	54,800	55	AS	0

** Business Activity- Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

State Ranking* - Hydrocodone

January 1 – September 30, 2012

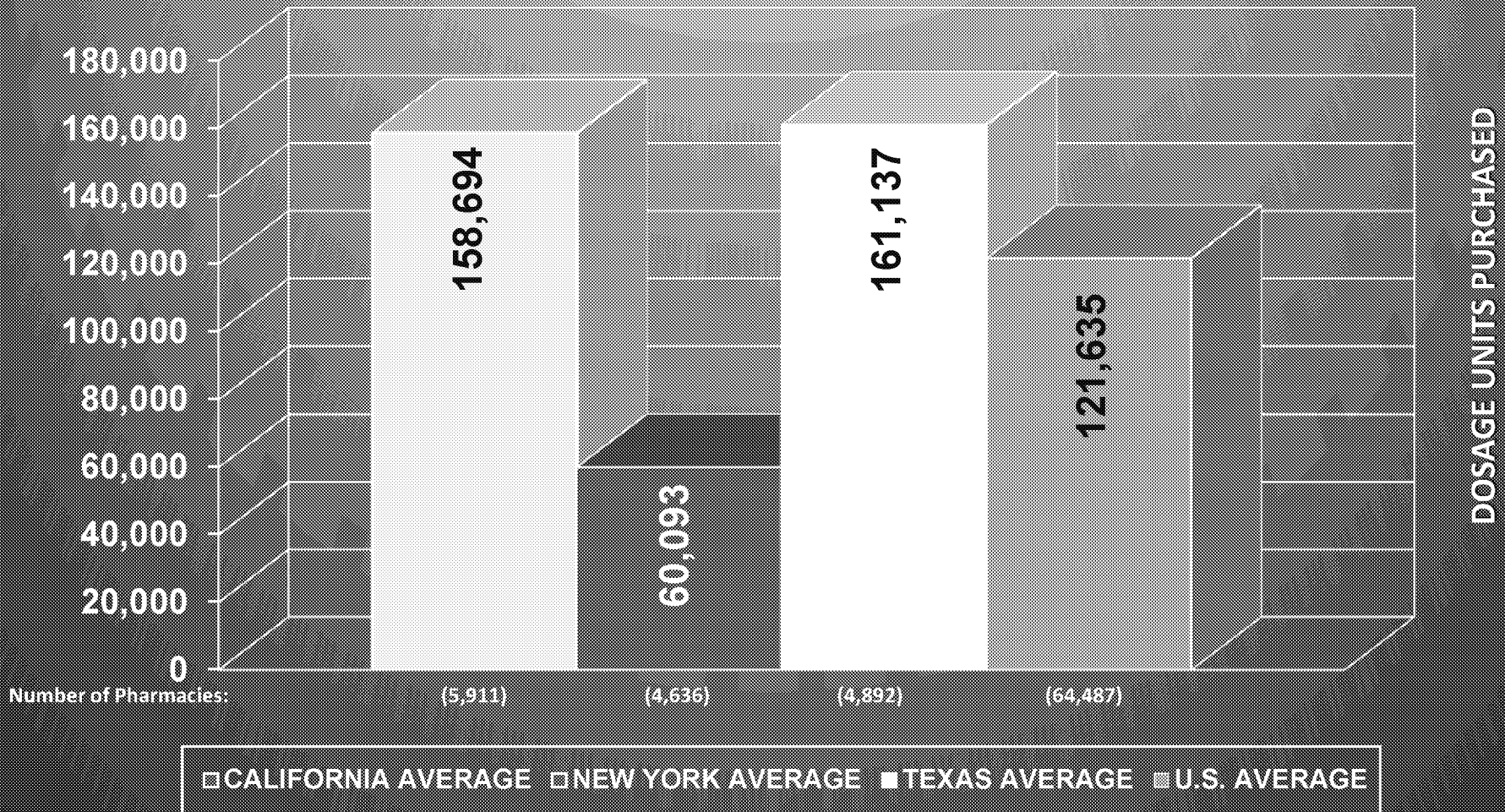
RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	752,243,210	12	PA	179,880,349	23	MS	95,040,930	34	MA	45,146,650	45	NH	11,372,160
2	TX	616,744,356	13	KY	174,997,631	24	AR	91,577,120	35	MD	39,757,136	46	WY	9,801,690
3	TN	372,321,936	14	NC	168,721,190	25	OR	89,644,605	36	ID	39,144,850	47	AK	8,914,452
4	MI	316,860,884	15	MO	155,533,410	26	WI	83,864,540	37	NM	34,014,930	48	ND	8,192,140
5	FL	272,756,535	16	OK	142,561,470	27	KS	72,465,169	38	NE	28,350,230	49	DE	7,154,030
6	IL	233,059,530	17	LA	128,601,625	28	WV	68,151,620	39	CT	26,188,240	50	VT	5,672,450
7	OH	224,079,845	18	SC	119,274,940	29	CO	60,518,800	40	ME	22,443,390	51	DC	1,795,600
8	IN	216,475,192	19	NV	117,109,135	30	IA	53,580,034	41	MT	20,483,720	52	PR	1,421,520
9	GA	197,245,775	20	WA	113,082,770	31	MN	53,502,119	42	RI	15,836,670	53	VI	344,030
10	NY	191,672,460	21	VA	111,391,716	32	UT	46,820,190	43	HI	14,422,340	54	GU	183,400
11	AL	190,924,530	22	AZ	108,617,660	33	NJ	46,479,750	44	SD	12,077,710	55	AS	0

** Business Activity—Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

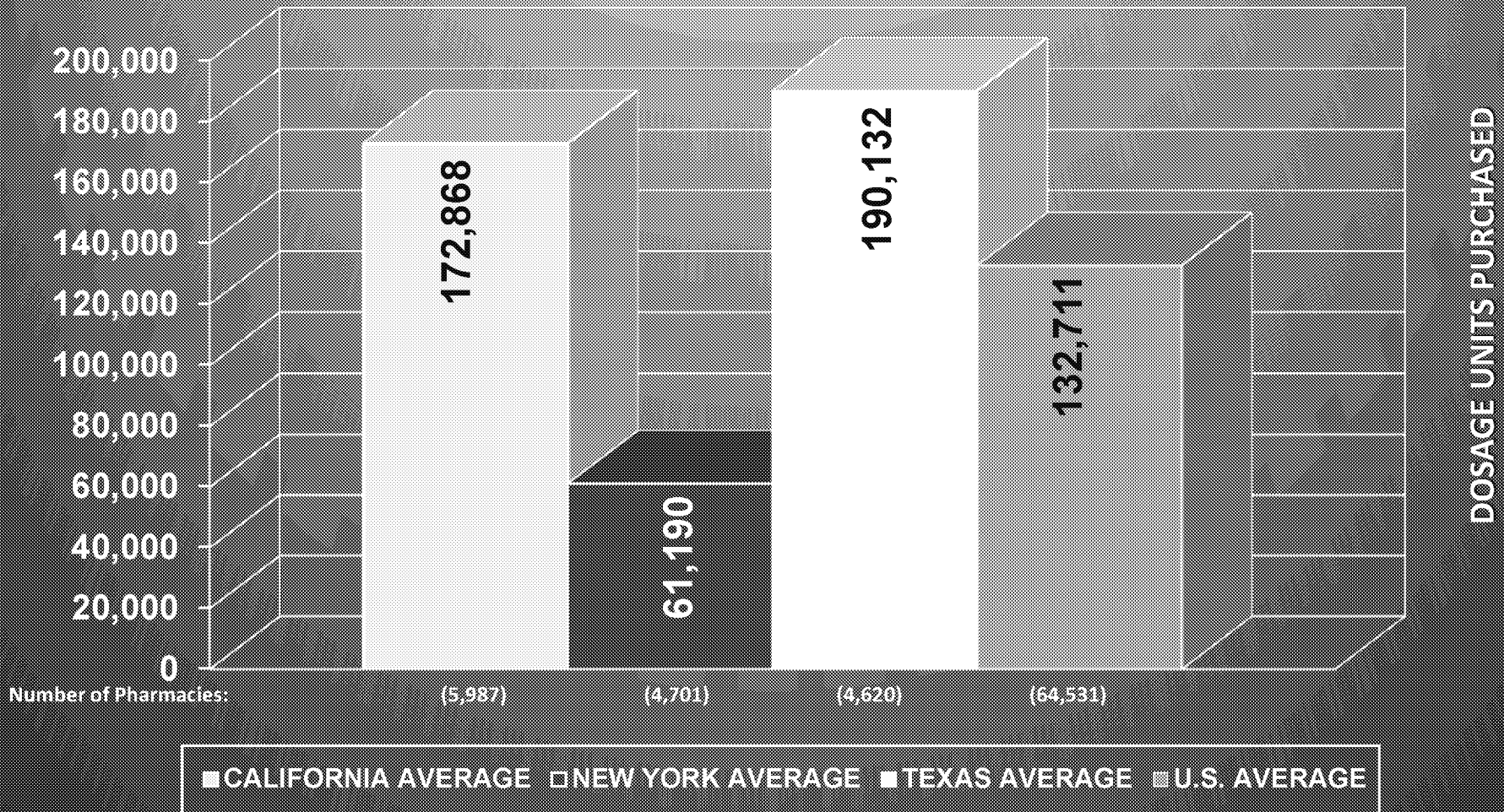
2010

Comparisons of Hydrocodone Sales to Pharmacies



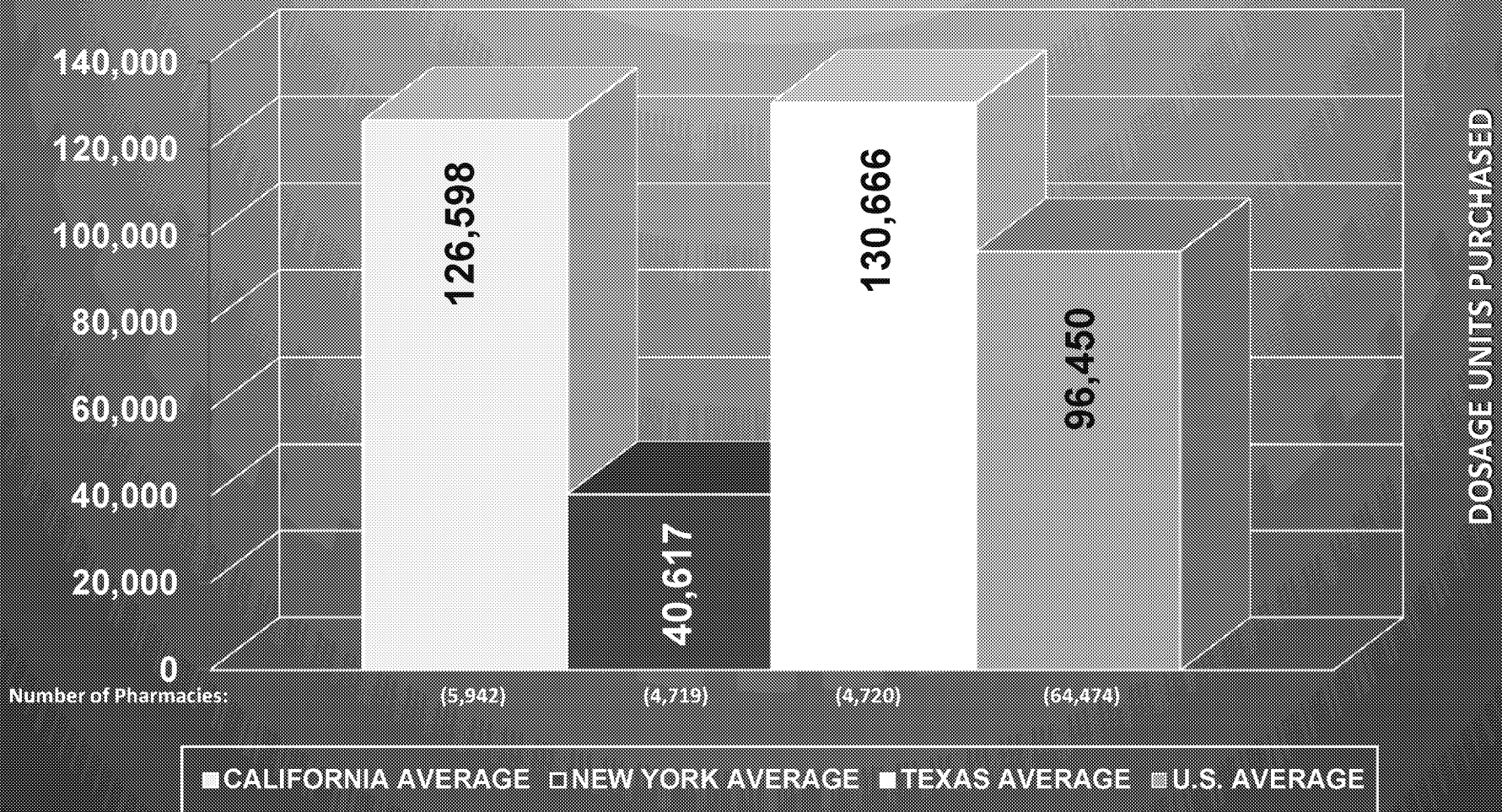
2011

Comparisons of Hydrocodone Sales to Pharmacies



January 1 – September 30, 2012

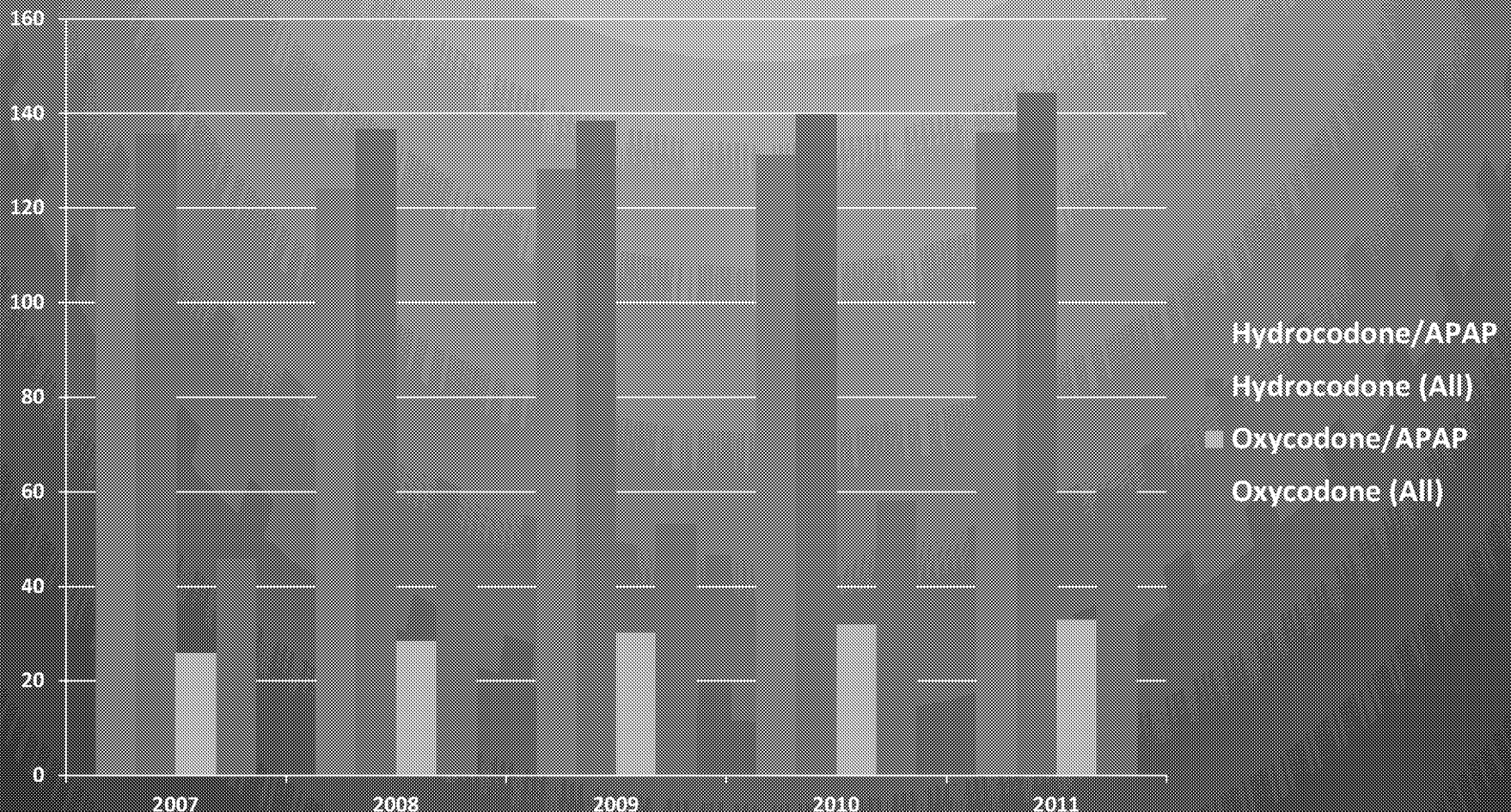
Comparisons of Hydrocodone Sales to Pharmacies



National Poison Data System (Formerly known as Toxic Exposure Surveillance System) – Total Annual Mentions of Toxic Exposures

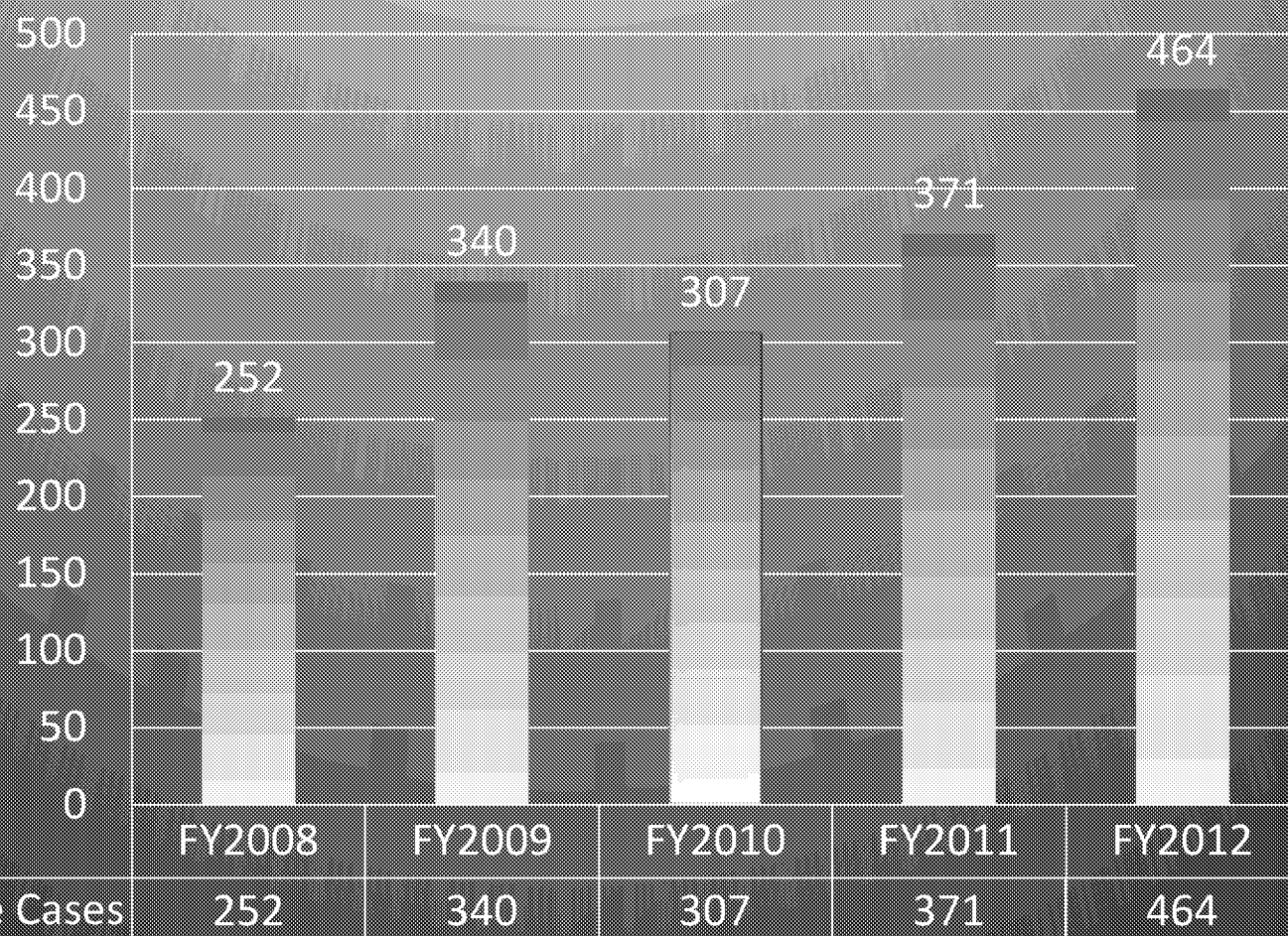
	Hydrocodone	Oxycodone
2001	15,191	9,480
2002	17,429	10,515
2003	19,578	11,254
2004	22,654	12,603
2005	22,229	13,191
2006	22,319	13,473
2007	24,558	15,069
2008	26,306	17,256
2009	27,753	18,396
2010	28,310	19,363
2011	30,792	19,423

U.S. Dispensed Prescriptions (IMS Data, Total RX's in Millions)



Source: IMS Health: National Prescription Audit

*Diversion Hydrocodone Cases** *FY2008 thru 2012*



*Source: SMARTS

Hydrocodone Combinations

CSA defines hydrocodone substance as Schedule II, while its combination products as Schedule III.

DEA has received a petition to reschedule CIII hydrocodone combination products to CII.

In 2004, DEA completed an initial review forwarded the data to DHHS with a request for scientific and medical evaluation and scheduling recommendation.

In 2008, HHS provided a scientific and medical evaluation

In 2009, DEA sent additional data to FDA/HHS and requested a scientific and medical evaluation.

Procedures to control a substance

- DEA receives a petition from an interested party (proceedings may also be initiated at the request of the AG or Secretary of HHS)
- Petition is reviewed and accepted
- DEA conducts initial 8-factor analysis review
- Documents and material gathered during the initial review and analysis of petition is sent to HHS/FDA with a request for a scientific and medical evaluation and a recommendation as to whether the drug should be controlled
- The recommendation and review document is received back from HHS/FDA

Factors determinative of control or removal from schedules (21 USC 811(c))

- (1) Its actual or relative potential for abuse
- (2) Scientific evidence of its pharmacologic effect, if known
- (3) The state of current scientific knowledge regarding the drug or other substance
- (4) Its history and current pattern of abuse
- (5) The scope, duration and significance of abuse
- (6) What, if any, risk there is to public health
- (7) Its psychic or physiological dependence liability
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter

Schedule II

- The drug or other substance has a high potential for abuse
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions
- Abuse of the drug or other substance may lead to severe psychological or physical dependence

Schedule III

- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I or II
- The drug or other substance has a currently accepted medical use in treatment in the United States
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence

The legislative history suggests the following in determining whether a particular drug or substance has a potential for abuse⁽¹⁾:

- a. Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
- b. There is a significant diversion of the drug or other substance from legitimate drug channels; or
- c. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
- d. The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has potential for abuse

1. (Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No 91-1444, 91st Cong., Sess.1 (1970) reprinted in U.S.C.C.A.N. 4566,4603): 120